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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**[CMS-3292-N]**

#### **Medicare Program; Announcement of the Approval of the American Association for Laboratory Accreditation (A2LA) as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the application of the American Association for Laboratory Accreditation (A2LA) for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for all specialty and subspecialty areas under CLIA. We have determined that the A2LA meets or exceeds the applicable CLIA requirements. We are announcing the approval and granting the A2LA deeming authority for a period of 4 years.

**DATES:** Effective Date: This notice is effective from **[INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]** to **[INSERT DATE 4 YEARS AFTER DATE OF PUBLICATION IN FEDERAL REGISTER]**.

#### **FOR FURTHER INFORMATION CONTACT:**

Cindy Flacks, (410)786-6520.

#### **SUPPLEMENTARY INFORMATION:**

## **I. Background and Legislative Authority**

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100-578). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, we may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

## **II. Notice of Approval of the A2LA as an Accreditation Organization**

In this notice, we approve the American Association for Laboratory Accreditation (A2LA) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for all specialty and subspecialty areas under CLIA. We have examined the initial A2LA application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that the A2LA meets or exceeds the applicable CLIA requirements. We have also determined that the A2LA will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of R. Therefore, we grant the A2LA approval as an accreditation organization under subpart E

of part 493, for the period stated in the “DATES” section of this notice for all specialty and subspecialty areas under CLIA. As a result of this determination, any laboratory that is accredited by the A2LA during the time period stated in the “DATES” section of this notice will be deemed to meet the CLIA requirements for the listed subspecialties and specialties, and therefore, will generally not be subject to routine inspections by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

### **III. Evaluation of the A2LA Request for Approval as an Accreditation Organization Under CLIA**

The following describes the process used to determine that the A2LA accreditation program meets the necessary requirements to be approved by CMS and that, as such, CMS may approve the A2LA as an accreditation program with deeming authority under the CLIA program. The A2LA formally applied to CMS for approval as an accreditation organization under CLIA for all specialties and subspecialties under CLIA. In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

#### **A. Subpart E--Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program**

The A2LA submitted its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its current laboratories and the expiration date of their accreditation, and a detailed comparison of the individual accreditation requirements with the comparable condition-level

requirements. The A2LA policies and procedures for oversight of laboratories performing laboratory testing for all CLIA specialties and subspecialties are equivalent to those of CLIA in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. The A2LA submitted requirements for monitoring and inspecting laboratories in the areas of accreditation organization, data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. The requirements of the accreditation program submitted for approval are equal to or more stringent than the requirements of the CLIA regulations.

Our evaluation identified the A2LA's requirements pertaining to waived testing, provider performed microscopy procedures, and moderate complexity testing that are more stringent than the CLIA requirements. The A2LA's requirements for high complexity testing are equivalent to the CLIA requirements. The A2LA will only accredit for waived tests or provider performed microscopy procedures if the laboratory is also applying for high or moderate complexity testing accreditation. Under the A2LA's requirements, laboratories performing any of these levels of testing will be held to the high complexity personnel requirements for all testing that the A2LA will accredit (high, moderate, waived or provider performed microscopy), as well as the requirements for nonwaived testing located in Subparts H, J, K, M, Q, and applicable parts of R.

In contrast, the CLIA requirements at §493.15 only require that a laboratory performing waived testing follow the manufacturer's instructions and obtain a certificate of waiver. The CLIA requirements at §493.19 require that a laboratory performing provider performed microscopy procedures meet personnel requirements located at

§493.1355 through §493.1365. The CLIA requirements at §493.20 require that a laboratory performing moderate complexity testing meet the personnel requirements located at §493.1403 through §493.1425.

B. Subpart H--Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

The A2LA's requirements are equal to or more stringent than the CLIA requirements at §493.801 through §493.865. For instance, the A2LA requires that laboratories conduct proficiency testing activities for both primary and secondary test systems for waived and non-waived testing. The CLIA requirement at §493.801(b)(6) requires proficiency testing activities for the primary test system and for non-waived testing only.

C. Subpart J--Facility Administration for Nonwaived Testing

The A2LA requirements for the submitted subspecialties and specialties are equal to the CLIA requirements at §493.1100 through §493.1105.

D. Subpart K--Quality System for Nonwaived Testing

The A2LA requirements are equal to or more stringent than the CLIA requirements at §493.1200 through § 493.1299. For instance, laboratories that are performing waived testing in addition to moderate or high complexity testing will need to meet all requirements in subpart K, Quality System for Nonwaived Testing. The A2LA has more specific requirements for laboratory information systems than CLIA. In addition, prior to adding a new test to the laboratory's accreditation, the A2LA requires the laboratory to submit performance specifications for review and approval.

E. Subpart M--Personnel for Nonwaived Testing

We have determined that the A2LA's requirements are equal to or more stringent

than the CLIA requirements at §493.1403 through §493.1495 for laboratories that perform moderate and high complexity testing. Under the A2LA's requirements, laboratories that perform moderate complexity testing must meet the personnel requirements for high complexity testing located at §493.1441 through §493.1495.

#### F. Subpart Q--Inspections

We have determined that the A2LA requirements for the submitted subspecialties and specialties are equal to or more stringent than the CLIA requirements at §493.1771 through §493.1780. The A2LA requires a two day onsite surveillance visit one year after the initial accreditation is granted. The A2LA requires annual review of all accredited laboratories. The laboratory is required to submit any updates on information about its organization, facilities, key personnel and results of any proficiency testing. Laboratories may be required to undergo an onsite surveillance visit if they do not submit their annual review documentation to the A2LA by the established 30 day deadline, if significant changes to the facility or organization have occurred, or if proficiency testing results have been consistently poor. The CLIA regulations do not have this requirement.

#### G. Subpart R--Enforcement Procedures

The A2LA meets the requirements of subpart R to the extent that it applies to accreditation organizations. The A2LA policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, the A2LA will deny, suspend, or revoke accreditation in a laboratory accredited by the A2LA and report that action to us within 30 days. The A2LA also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the A2LA's laboratory enforcement and appeal policies are equal to the requirements of part 493, subpart R as they apply to accreditation organizations.

#### **IV. Federal Validation Inspections and Continuing Oversight**

The Federal validation inspections of laboratories accredited by the A2LA may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by the A2LA remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

#### **V. Removal of Approval as an Accrediting Organization**

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of the A2LA, for cause, before the end of the effective date of approval. If we determine that the A2LA has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which the A2LA would be allowed to address any identified issues. Should the A2LA be unable to address the identified issues within that timeframe, we may, in accordance with the applicable regulations, revoke A2LA's deeming authority under CLIA.

Should circumstances result in our withdrawal of the A2LA's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

#### **VI. Collection of Information Requirements**

This notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with the accreditation process for clinical laboratories under the CLIA program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB approval number 0938-0686.

**VII. Executive Order 12866 Statement**

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.



CMS-3292-N

**Authority:** Section 353 of the Public Health Service Act (42 U.S.C. 263a).

**Dated:** March 14, 2014.

**Marilyn Tavenner,**

Administrator,

Centers for Medicare & Medicaid Services.

**BILLING CODE 4120-01-P**

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